Medical Devices Fee Consultation Workshop

Citadel Ottawa Hotel and Convention Centre
March 25-27, 1998

REFERENCE DOCUMENTS

- Proposed Agenda
- Issues for Workshop
- Background Information
- How to Calculate Class III and Class IV Fees
- Impact Discussion Paper
- Fees to Be Paid in Respect of Medical Devices Regulations

104-05607/

Client Name Here

Workbook

Title Here

Sub-Title
and/or Date Here

Medical Devices
Cost Recovery Consultation Workshop
March 25-27, 1998

Location: Cidatel Hotel

Proposed Agenda

Wednesday, March 25, 1998

18:00	❑	*Dinner (Frontenac Room)*	
		A. Focus on Purpose	
19:30	❑	Opening Remarks • Context • Purpose and Expected Outcomes	Dann Michols
	❑	Review of the Agenda	Dan Normandeau (Facilitator)
	❑	Introductions and Expectations	
		B. Focus on Progress since August 1997: Updates	
	❑	Update on Changes to Regulations • what was done • response to August concerns • what is being done to get ready	Beth Pieterson
	❑	Update on Changes to Cost Recovery Proposal • response to recommendations in BIT • response to August concerns	Andy Butterfield
	❑	Other • Issues to address	
21:00	❑	Conclusion of Evening Session	

Thursday, March 26, 1998

07:30	❑	*Continental Breakfast (outside plenary room)*	

08:30 ❑ *Review of the day's Agenda*

❑ *Overview Presentation of the Fee Regulations* *Cindy Evans*

- *how the fee regulations work*
- *when they come into force*
- *overview of underlying principles of fee structure*

C. Focus on Issue 1: The Fee Structure

09:00 ❑ Breakout Session

- Expectation
  That advice will be provided regarding the proposed system of cost recovery, the appeal system and the elements of the review which have separate fees.

- Questions
  1. Are there any outstanding concerns related to the underlying principles in
     defining the fee structure and the approach described in the draft regulations?
  2. Are there any outstanding concerns related to the approach taken for the
     pre-market licensing fees?
  3. Are there any outstanding concerns related to the approach taken for the device
     licensing renewal fees?
  4. Are there any outstanding concerns related to the approach taken for the
     establishment licensing and licensing renewal fees?

  And what suggestions do you have for improvement?

❑ Health Break (each group breaks at their convenience)

11:00 ❑ Plenary - Feedback session

12:00 ❑ Lunch

D. Focus on Issue 2: Implementation of the Fee Regulations

13:00 ❑ Recap of the Overview of the Implementation Issues

13:10 ❑ Breakout Session

- Expectation
  That advice will be provided to TPP on implementation issues which have not been addressed, and on the adequacy of the implementation plans presented. The timing of the coming into force of various regulatory requirements will not be on the table for discussion.

- Questions
  1. Are there potential implementation problems which have not been addressed? If so, how would you propose to deal with them?
  2. Several situations and how TPP intends to address them have been presented. Are there suggestions to improve the process suggested?

14:45 ❑ Health Break

15:00 ❑ Plenary - Feedback Session

16:00 ❑ Assessment of the Day and Closure — Dan Normandeau

18:00 ❑ Dinner

Friday, March 27, 1998

07:30 ❑ Continental Breakfast (outside plenary room)

08:30 ❑ Review of the Day's Agenda — Dan Normandeau

E. Focus on Issue 3: Fee Reductions and Fee Exemptions

08:45 ❑ General overview of fee reductions and fee exemptions — Cindy Evans

❑ Presentation of the framework for the group discussion

09:00 ❑ Breakout session

- *Expectation*
  That stakeholders will provide guidance to TPP on fee reduction provisions and fee exemptions which have been included in the draft regulations. Feedback on the anticipated impact will be helpful to the TPP.

- *Questions*

1. Are there improvements which could be made to the 3 fee reduction provisions set out in the draft regulations? If so, provide improvements or alternative approaches.
2. Are there suggestions for improvement or alternative approaches for the exemption of certain pre-market review activities?
3. Are there suggestions for improvement or alternative approaches for the exemption of authorization activities?
4. What other activities, if any, should be exempted from the fees?

10:45	❑	Health Break	
11:00	❑	Plenary - Feedback Session	
12:00	❑	Recap of Key Workshop Results and Next Steps	Cindy Evans Beth Pieterson
12:15	❑	Evaluation of the Consultation Workshop	
12:20	❑	Closing Remarks	Dann Michols
12:30	❑	Close	

MEDICAL DEVICES FEE CONSULTATION WORKSHOP

ISSUES FOR WORKSHOP

The following are topics which form the focus of discussion and break-out sessions at the workshop. Details are given in the subsequent pages.

Issue 1: Fee Structure

Issue 2: Implementation issues

Issue 3: Fee Reductions and Fee Exemptions

Issue 1: Fee Structure

The proposed fee regulations set out a fee structure which is the result of consultation since the draft fee structure was presented in August 1997. The proposed fee regulations have been provided to workshop participants.

Considerations

- The fee structure must be as fair as possible yet balanced against complexity.

- The fees themselves must respect issues such as:
  - relationship to costs
  - not presenting an unacceptable financial burden to industry
  - not interfering with Programme objectives

- Three different types of fees will be charged. These types include fees for the review of information to obtain a licence number for class II, III and IV devices, which signifies market approval for a medical device, a fee for annual renewal of the device licence and a fee for establishment licensing for importers and distributors of class I to IV devices and certain manufacturers of class I devices.

- The fee for pre-market review will be based on the type and amount of information required to be reviewed which will be based on risk management principles.

- The annual fees for device license renewal and establishment licensing and renewal will cover the cost of the licensing activities and the costs of post market surveillance activity.

Expectations

That advice will be provided regarding the proposed system of cost recovery, the appeal system and the elements of the review which have separate fees. Fee reductions will be addressed separately.

Issue 2: Implementation of the Fee Regulations

The implementation schedule of the fee regulations matches the phased implementation of the regulatory requirements in the new Medical Devices Regulations which are targeted for publication in Canada Gazette Part II in May 1998.

Considerations

- Within the restrictions of a regulatory environment, the TPP and industry are moving from an existing regulatory framework and fee regulations to an improved regulatory framework and associated fee regulations.

- This combined effect of new regulations and fees is a concern for many firms. A closer examination shows that while individual situations vary, the new regulations will actually reduce requirements in several areas and remain essentially unchanged in others.

- TPP is committed to mitigating the impact of the new Regulations through phased introduction, provision of guidelines and open communication where possible and appropriate.

Expectations

That advice will be provided to the TPP on fee implementation issues which have not been addressed, and on the acceptability of the fee implementation plans presented. The timing of the coming into force of various regulatory requirements in new *Medical Devices Regulations* will not be on the table for discussion.

Issue 3: Fee Reductions and Fee Exemptions

As in most cost recovery elements in the TPP, there have been reasons to develop fee reduction provisions to reduce the negative impacts for specific products which have low sales or for small companies. In addition, several fee exemptions have been proposed

Considerations:

- Fees for various activities must respect Treasury Board's cost recovery principles and must be equitable for all companies and all device sectors.
- Any fee reduction provision must be simple to administer.
- When a fee reduction or a fee exemption is granted the activity undertaken is still a cost to the TPP.
- In the proposed fee regulations, several subsets of pre-market review activities are not subject to the fees. These include administrative changes and certain review component fees for submissions which follow an authorization for investigational testing.
- The draft fee regulations do not prescribe fees for certain authorization activities. These include authorization for custom-made devices and medical devices to be imported or sold for special access (Part 2) and medical devices for investigational testing involving human subjects (Part 3).

Expectations:

That stakeholders will provide feedback to the TPP on fee reduction provisions and fee exemptions which have been included in the draft regulations.

March 19, 1998

Background Information
Medical Devices Cost Recovery Consultation Workshop
March 25-27, 1998

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1. Introduction

Input provided by stakeholders at this workshop will be used to revise, as appropriate, the fee regulations to be published in Part II of Canada Gazette in June 1998. The fee regulations are targeted to come into force July 8, 1998.

The terminology and references to regulatory sections in the *Medical Devices Regulations* are linked to the terminology and section numbers seen in the February 1997 publication of the regulatory framework in Canada Gazette Part I (available on the TPP Web Site). The final fee regulations will reference the final version of the regulatory framework. For example, although the draft fee regulations make reference to medical device and establishment "registration", this will be revised to medical device and establishment "licensing" in accordance with the final regulatory framework.

2. Summary of the Proposed Medical Devices Regulations and Associated Cost Recovery

2.1 Medical Device Regulations

The Medical Devices Regulations set out the requirements governing the sale, importation and advertisement of medical devices. The goal of the Regulations is to ensure that medical devices distributed in Canada are both safe and effective.

The purpose of the proposed regulatory initiative, published in Canada Gazette Part I on February 15, 1997, is to replace the Medical Devices Regulations which have been in force since 1975, with a new set of Medical Devices Regulations that are consistent with contemporary regulatory philosophy.

The new Regulations stem from a 1991-1992 review of the Department's Medical Devices Program (now part of the Therapeutic Products Programme (TPP) which recommended that the Programme focus on regulating medical devices on a risk assessment and risk management basis. An implementation plan was then developed to act on the recommendations. That plan was founded on two principles: 1) that the level of scrutiny afforded a device should be dependent upon the risk that the device presents, and 2) that the safety and effectiveness of medical devices can best be assessed through a balance of quality systems requirements, pre-market scrutiny and post-market surveillance.

In developing these Regulations, and consistent with the recommendations from the 1991-1992 review, the Programme conducted extensive examination and evaluation of regulatory systems for medical devices in other jurisdictions (United States, European Union, Japan, Australia). Emphasis was placed on developing requirements which are harmonious[1] with those of our international trading partners and eliminating, to the greatest extent possible, requirements unique to Canada. Adoption of harmonious regulations in Canada will, on the one hand, raise the level of regulatory scrutiny for devices sold in Canada to levels currently exercised in the countries noted above. This will provide greater assurance of the safety and effectiveness of medical devices

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[1] Identical requirements are generally not feasible or appropriate due to differences in the medical, regulatory and legislative systems in Canada and elsewhere.

sold in Canada. On the other hand, harmonization will allow meaningful negotiations towards Mutual Recognition Agreements (MRA) to occur, thereby eliminating barriers to trade. MRAs, once operational, will allow devices to be assessed in one jurisdiction and placed on the market in all other jurisdictions party to the agreement without further assessment. The elimination of duplicative assessments will also have the effect of significantly reducing compliance costs to both industry and government and allow quicker introduction of new products, which benefits both patients and industry. **The Regulations have been developed with these principles in mind and take into account extensive consultations which have taken place to date with interested stakeholders.**

A brief summary of the Regulations published in Canada Gazette, Part I, February 1997, including changes which will appear in the final Regulations in May 1998, follows:

1. The Regulations set out a system for classifying medical devices into one of four classes; class I representing the lowest risk devices and class IV representing the highest risk devices.

2. Device manufacturers must licence class II - IV devices before they sell in Canada. Sale of unlicensed devices is prohibited. Device licensing involves submission of information to the Programme (refer to items 4 and 5). Annual validation of the sale of Class II, III and IV devices will be required. This validation will consist of attestation by the licence holder as to the sale status and quality system status of the device. There will be no requirement to obtain a licence for class I medical devices.

3. Importers and distributors of class I to IV medical devices must hold an establishment licence as well as Class I manufacturers who do not import or distribute solely through a person who holds an establishment. Establishment licensing involves submission of information to the Programme. Sale of devices by unlicensed importers and distributors is prohibited.

4. Devices imported or sold in Canada must be labelled in accordance with specified labelling requirements and must meet eleven fundamental safety and effectiveness requirements. Manufacturers must possess evidence that their devices meet those requirements. Further, manufacturers must provide assurance to the Programme that the requirements have been met. The degree of information which must be submitted to provide that assurance is proportional to the class of the device. For example, Class IV devices require more information to be submitted than class III devices; class III devices require more information to be submitted than class II devices.

5. Manufacturers must provide evidence that class II, III and IV devices they sell in Canada are produced in accordance with a certified quality system.

6. The post-market surveillance aspect of the Regulations requires manufacturers, importers and distributors to keep distribution records and to have written procedures to investigate problems and to recall defective devices from the market.

7. Manufacturers and importers must report to the Programme serious problems which have occurred involving the use of devices they sell.

8. There are provisions to facilitate the tracking of certain implanted devices so that recipients of those implants may be notified of pertinent post-implant information. Schedule II to the regulations will

identify devices subject to this requirement. Devices identified on this Schedule include heart valves, annuloplasty rings, implantable pacemakers and leads, and devices of human origin such as human dura mater.

9. There are provisions governing investigational testing of devices in Canada. Manufacturers will be required to obtain authorization from the Programme prior to conducting investigational testing involving Class II, III and IV devices. The provisions will require investigators to provide a written undertaking to the manufacturer that they will conduct the investigation in accordance with the protocol provided and that they will advise the manufacturer and the Programme of any serious problems which may result from the use of the investigational device.

10. There are provisions to exempt custom-made devices and devices sold under the special access program from most of the requirements of the Regulations, beyond basic requirements which must be met to obtain authorization for their sale.

11. There are transitional provisions to bring the Regulations into effect. The new Regulations, with some exceptions, will take effect on July 8, 1998. The exceptions relate to establishment licensing, quality systems requirements and device licensing on as follows:

a) Establishment licensing requirements take effect on January 1, 1999 meaning establishments must be licenced by that date.

b) Quality system requirements take effect on July 1, 2001, meaning that new licence applications must include an attestation that their devices are fabricated in accordance with a quality system as of that date.

c) Manufacturers of devices which are being sold in Canada when the new Regulations take effect will be required to licence those devices during the grace period of July 8, 1998 to February 1, 1999. Manufacturers wishing to introduce devices onto the market after the new Regulations take effect will need to licence devices prior to selling them; there is no grace period for those devices.

For class III or IV devices which were being sold in Canada when the new Regulations take effect, pre-market requirements of the device licence will be deemed to have been met if the devices were being sold in compliance with specified provisions of the old Regulations.
Class I devices will not be required to be licenced.

The scope of these Regulations remains virtually unchanged in that all medical devices will be subject to the Regulations, with the minor exception of medical devices for use on animals which will only be subject to the Food and Drugs Act. The major difference is the focus of the new Regulations and their emphasis on the risks inherent in medical devices. Under present requirements only 5 - 10 per cent of medical devices are subject to pre-market scrutiny prior to marketing in Canada, whereas under these Regulations, approximately 60 per cent of medical devices will undergo some form of pre-market scrutiny before authorization for sale in Canada is granted. A significant portion of this pre-market scrutiny is in the area of quality system audits.

The Programme is committed to implementing an auditing system whereby audits would be conducted on behalf of the Program by independent third party audit organizations. Auditing organizations will be

assessed to ensure their competency to conduct audits on behalf of the Programme. Due to the number of domestic and international auditing organizations currently working in this field, it is not anticipated that manufacturers will experience any marketing delays in having acceptable quality systems certified.

With respect to the pre-market scrutiny of scientific/technical data, the Programme will undertake an increased workload. The current 5 - 10 per cent of medical devices which undergo scientific/technical scrutiny will increase to 20 per cent. For approximately three quarters of these devices (class III), the Programme will review summarized safety and effectiveness information. For the remainder (class IV), a detailed review of data will be required as is currently done for Part V devices. Since 1995, the TPP has consistently met performance standards acceptable to industry for the review of applications for the issuance of a Notice of Compliance pursuant to Part V of the current Regulations. The Programme is confident that reviews to be conducted with this increased workload will continue to be done within acceptable time frames if adequate resources are available. Performance standards are being developed in consultation with the medical devices industry. These standards will be implemented and performance will be measured and reported against them.

2.2 Cost Recovery

It is government policy to implement user charges for services that provide identifiable recipients with direct benefits beyond those received by the general public. The Therapeutic Products Programme is implementing cost recovery in accordance with this policy in order to obtain stabilized funding for its activities.

In synchrony with the introduction of the new *Medical Device Regulations*, fees will be charged for activities associated with pre-market review of data, establishment licensing, and device licensing. A costing analysis of these activities was done in order to ensure that the fees are realistic and fair. The proposed fees fall into three main categories, each of which recovers a portion of Programme costs for distinct activities as shown in the following table.

Fee Category	Activities Covered	Approach
initial medical device (product) licensing	-pre-market assessment / review	components based on information required for different submission types
medical device (product) licensing renewal	-product licensing maintenance - quality systems program maintenance -post-market activities	annual fee
establishment licensing and licensing renewal	-establishment licensing maintenance -post-market activities	annual fee

Fee reduction provisions have been included in the draft fees regulations to mitigate economic harm and to ensure availability of low sales devices

In addition to this consultation workshop, the proposed Fee Regulations will be posted on the TPP web site and published in Canada Gazette Part I so that all interested parties will have an opportunity to comment.

The fee schedule (section 3) is relatively straightforward; however, some explanation is in order. As shown in the above table there are three basic fee categories. The most complex are the initial product licensing fees. Fees apply based on what information is submitted for review, and this is determined by the *Medical Devices Regulations.* More than one component fee may apply. The minimum fee applicable will be the initial licence fee, and this is applicable to classes II, III and IV. The fees for Class III and IV device reviews will include additional component fees.

An additional, annual fee will be charged for renewal of a medical device licence (similar to drug annual notification). As shown in the above table, this fee is distinct from and recovers the costs of different activities that the initial medical device licence fee charged as part of the pre-market licence process.

A third fee is for establishment licensing, and is an annual fee associated with the initial and annual renewal of

an establishment licence. Again, the fee is intended to recover part of the cost of different activities than those recovered by the first two fees

3. Fee Structure

The table below provides a summary of the fees described in the draft fee regulations. For the specific wording of the components, refer to the draft fee regulations.

Item	Submission Component	Device Class	Fee (CDNS)
1	materials/intended use/market history	IV	$140
2	risk assessment	IV	$1,000
3	device specifications	IV	$680
4	production process specifications	IV	$510
5	quality assurance procedures and specs.	IV	$850
6	preclinical-clinical studies (IVDD)	IV	$5,970
7	preclinical-clinical studies (non-IVDD)	IV	$7,670
8	process validation studies	IV	$850
9	software validation studies	IV	$2,020
10	labelling	IV	$170
11	biologically sourced component	IV	$2,620
12	near patient testing	IV	$2,410
13	materials/intended use/market history	III	$140
14	safety and effectiveness studies	III	$1,470
15	labelling	III	$170
16	near patient testing	III	$440
17	licensing devices already notified	II, III, IV	$110
18	initial licensing for new devices	II, III, IV	$200
19	annual device licence renewal	II, III, IV	$100
20	initial establishment licensing	all classes	$2,530
21	annual establishment licensing renewal	all classes	$2,120

3.1 Pre-market (Screening and Examination) Fees

Manufacturers will be required to submit a licence application for new Classes II, III, and IV medical devices intended for sale on the Canadian market. A device licence must be renewed annually. The basic fee of $200 applies to all new medical devices. For devices currently on the market which have been either notified (Part II) or hold an NOC (Part V) the basic fee is $110.

The definition of what is considered to be one medical device for the purpose of licensing is described in the February 2, 1998 draft titled "Guidance on How to Determine Device Licence Type ". This draft guideline is available on the web site.

Fees for Review of Specific Information Items - Class III and IV Devices

Licence fees for new Class III and IV devices are based on the information required for review, as determined by the Regulations. In addition to the base licence fee, applications for new Class III and IV devices will be subject to additional pre-market review component fees. The applicable fees will vary depending on the number of data components which require review. Review items are priced individually and may differ according to the nature of the device as in the case of preclinical studies for In Vitro Diagnostic Devices (IVDDs) versus non-IVDDs.

Class III

The fee for typical class III licence application would be the $200 basic fee plus the sum of component fees 13, 14 and 15 for a total of $1,980.

Class IV

The fee for a typical class IV licence non-IVDD application would be the $200 basic fee plus the sum of component fees 1, 2, 3, 4, 5, 7, 8, 9 and 10, for a total of $ 14,090.

The fee for a typical class IV licence application for an IVDD would be $200 basic fee plus the sum of component fees 1, 2, 3, 4, 5, 6, 8, 9 and 10, for a total of $ 12,309.

Amendment Fees

A "significant change" to a licensed Class III or IV device, triggers the requirement for a licence amendment and the associated fee. A draft Guidance Document has been prepared for "significant change". Two examples of significant change are described in the Guide: a change to indication for use, and a change to device design. The fee for a licence amendment will be based on the data components which are required to support the requested change.

Any of the following changes to a device licence are categorized as "administrative amendments" and are not subject to an additional fee:

a) change in the name of the manufacturer;
b) change in the name of the device;
c) change in the medical device identifier; and
d) for a class II device, a change in the medical conditions, purposes or uses for which the device is manufactured, sold or represented unless this change affects the class of this device.

Timing of Payments

Where the total fee is $5000 or less, the payment must be included with the licence appli ation. This group will include all class II and class III applications and some amendments for class IV applications. Where the total fee is greater than $5000, no payment must be included up front with the application. The sponsor will be invoiced at the end of the screening period. If the application does not pass screening, the sponsor will be billed for 10% of the total fee. If the application passes screening and is therefore accepted for review, the sponsor will be billed for 75% of the total fee with the remaining 25% billed when the review has been completed.

3.2 Annual Medical Device License Renewal Fees

Class II, III, and IV medical devices will all be subject to the same annual licence fee ($100). An invoice will be sent to licence holders for the sum of all the licenced products. This will be done in November of each year beginning in November 1999.

3.3 Establishment Licence and Licence Renewal Fees

The establishment licensing fees are straightforward. There is a fee for the initial application for an establishment license and an annual fee to renew the licence. The requirement to have an establishment licence will come into force January 1, 1999. There will be a two month period, from November 1, 1998 to January 1, 1999 to submit the information necessary to apply for the licence.

The purpose of this regulatory requirements for establishments is:

- To ensure that the Therapeutic Products Programme is made aware of the identity of establishments that are selling devices in Canada.

- To require establishments to provide some assurance to the Programme that regulatory requirements related to post-production activities have been met.

Who must have a licence?

The establishment licensing regulations apply to any person who imports or distributes a class I, II, III or IV medical device and to manufacturers of class I devices who do not import or distribute solely through a person who holds an establishment licence. The scope of the regulations captures the sale of devices to a retailer, a health care facility, or another distributor.

A manufacturer of class II, III or IV devices located outside of Canada can distribute a licenced device of their own manufacture directly to a consumer or user, or to a health care facility or retailer without licensing. This is equivalent to the rights of a domestic manufacturer to distribute their own products without an establishment licence. If, however, the shipment is divided, parceled or allotted in Canada to other persons, then the person responsible for this distribution must licence their establishment.

Who does not require a licence?

A person is not required to licence their establishment if they are a retailer, a health care facility, the manufacturer of a class II, III or IV product, if the definition of sale does not apply, or the products sold are not medical devices.

The Regulations exempt the manufacturer of a class II, III or IV device because the necessary information is collected through the medical device product licensing process. If manufacturer X sells (distributes) a device that is licenced by manufacturer Y, then manufacturer X is not exempt from establishment licensing for this device. In this case, the distributing manufacturer must register as an establishment because they become a distributor.

The Regulations exempt the manufacturer of a class I device who imports or distributes solely through a person who holds an establishment licence because the necessary information is collected through the establishment licensing process of that importer or distributor of the device. The requirement for a subset of class I manufacturers to hold an establishment licence is a significant decrease in regulatory burden in comparison with the previously proposed requirement for all class I manufacturers to licence individual products.

A retailer who distributes directly to the general public and does not manufacture is exempted from the requirement to hold an establishment licence. However, if a retailer distributes to another retailer or distributor, then they must licence as a distributor.

Other activities which are exempt from the requirement to hold an establishment license include the following:

- Manufacturers, importers or distributors of veterinary devices. A veterinary device is subject to the Food and Drugs Act, but it is not included in the regulatory definition of a medical device and is therefore not subject to the Medical Devices Regulations.

- A "dispenser" as defined in the Regulations is exempt from the establishment licence provisions.

- Contractors are exempt if they perform a function or service on a product on behalf of another person who is assuming legal responsibility for the product. They do not meet the definition of manufacturer for the product. For example, a person would be exempt if they design, manufacture, assemble, process, label, package, refurbish, or modify a device on behalf of another person who sells the product under their own name and has licensed the device. Contract sterilizers, contract designers, contract software developers re-packages or re-labellers would not be required to licence their establishment.

- A person who imports a product for their own consumption or use.

How many Establishment Licences Do you Need?

The following terms have been defined to specify the relationships between applicants, licensees, and establishments.

Each **establishment** needs to hold a **licence** to import, sell or distribute medical devices in Canada.

An **establishment** may have one or more **sites**. There are many companies that have only one distribution site and there are others that have multiple sites. Where one company is the sole controller of several distribution sites, ordinarily only the primary head office of the organization would need to apply for a licence. It is expected that the head office would maintain records of the distribution sites they control. Each licence application will indicate number of sites covered by that licence together with all the required information and attestations for each site on the application.

A single distribution point is a **site** which must be covered by a valid establishment licence. A site has one postal address that is listed in a licence. In some cases a site may have more than one building. Business locations where recall, problem reporting, records keeping, warehousing and distribution activities are centered need to be included in the list. An office performing only sales functions would not be required to be listed.

An **application for an establishment license** is submitted to TPP by one **applicant** and may list more than one distribution site. An applicant is responsible for providing all required information and attestations for all the sites in the application.

An **establishment licence** is a document issued by TPP which may cover more than one site. The licence is issued to the applicant who then becomes the **licensee**, in the sense of being the person ultimately responsible for maintaining compliance with the conditions of the licence. The licence document itself does not list the sites. All licences have the same format regardless of the number of sites they cover. The site list is an administrative annex to the licence, so that it can be amended as sites change annually, without having to amend the licence. Each establishment licence will be subject to one applicable fee.

4 Fee Reduction Provisions

Subsequent to the discussions with stakeholders at the August 1997 consultation workshop, and stemming from the recommendations of the Business Impact Assessment (December 19, 1997) fee reduction provisions have been included in the draft fee regulations.

Provision 1

At the time of initial application for a medical device licence, if the fee to be paid is expected to exceed 5% of the anticipated gross revenue from the first two years of sale of the device, the applicant is eligible for a fee reduction. This model stems from the existing medical device fee reduction provision for Part V reviews.

For class II devices, the fee reduction provisions is structured to minimize administrative burden. Where the data presented support the eligibility for a fee reduction, the fee is reduced from $200 to $100. All class II devices which qualify for a fee reduction will be subject to the same fee. There is no requirement to submit financial records at the end of the two year period, instead, the TPP will be conducting audits to verify eligibility for fee reductions.

For class III and IV devices, because of the larger fees involved and the differences in potential fees, the reduced fee will be based on 5% of the anticipated 2 year gross revenue. A higher level of information to support the fee reduction request will be required by the TPP. At the end of the two year fee verification period, the onus is on the applicant to submit certified financial records.

Provision 2

As part of the annual medical devices licence renewal fees, individual products are eligible for a reduced fee. The full proposed fee of $100 will be reduced to $50 if the medical device had gross revenue of less than $20,000 in the previous fiscal year. This provision will minimize the impact of the fees on "niche" or low sales volume products.

Provision 3

In addition to provision 2 above which addresses individual medical devices, a second fee reduction provision has been included, which addresses the potential impact of the fees on small businesses. Where a company's total product fees, which may include both $100 and $50 fees is greater than 1.5 percent of the total annual gross revenue of the company in the previous fiscal year, the total fee will be reduced to 1.5 percent.

5 Activities Exempted from Fees

Several activities which are part of the pre-market authorization of medical devices are not subject to individual fees including administrative changes for all classes of products. The cost to the Programme of processing these changes will be captured as part of the annual licence renewal fees. This will decrease the administrative burden for both TPP and applicants.

Where a company has applied for an authorization to conduct investigational testing, a review is conducted on certain data related to the product at the time of application for authorization. The proposed fee regulations include an exemption whereby a class III product which has been reviewed for authorization for investigational testing will not be subject to the component number 1 of the fee structure ($140). The work involved in the review of the description of the medical device, the materials used and the summary of reported problems in other countries has already been completed at the time of application for authorization for investigational testing. Similarly, for a class IV product, item 1 ($140, same component as class III) and 2 ($1000, risk assessment) do not apply if the product was granted authorization for investigational testing.

The draft fee regulations do not prescribe fees for the authorization requirements in part 2 and 3 of the regulatory framework. Therefore authorizations for custom-made devices and medical devices to be imported or sold for special access (Part 2) and authorizations for medical devices for investigational testing involving human subjects (part 3) are not subject to fees.

6 Implementation

6.1 Phased Implementation of Regulatory Requirements and Fees

A. Obtaining the Medical Devices (Product) Licence

(i) As of July 8, 1998 all new products must hold a licence before they are sold in Canada

(ii) As of February 1, 1999 products which were notified or held an NOC as of July 7, 1998 must hold a licence. There is a 7 month grace period (July 8, 1998 to February 1, 1999) to obtain licences for products already on the market as of July 8, 1998.

(iii) Fees are payable with the application for a product licence. Applications with fees greater than $5000 will be invoiced.

B. Annual Medical Devices (Product) Licence Renewal

(i) First round of product licence renewal will occur November 1, 1999. Annually, each existing product licence will be renewed for the period of November 1st to October 31st.

(ii) The annual product licence fee invoice will be based on the number of medical devices licenced by the company as of November 1st. It should be noted that if companies choose to licence currently marketed products at the end of the 7 month grace period (ie. January 1999), licence holders will pay both the initial fee and the first annual fee in the same calendar year.

C. Obtaining an Establishment Licence

(i) The application period for obtaining the initial Establishment Licence is from November 1, 1998 to January 1, 1999. All establishments must hold a licence as of January 1, 1999.

(ii) The Establishment Licensing fees will be payable starting January 1, 1999. Companies will be invoiced.

D. Annual Establishment Licence Renewal

(i) The Establishment Licences will be renewed annually for the period from January 1st to December 31st. The first establishment Licence renewal will occur in January 2000.

(ii) Companies will be invoiced January of each year for licences which are renewed.

6.2 Transition from NOC/Notification Process to Licensing Process

Transition from Existing to Revised Regulatory Framework and Fees

Item	Status as of July 8, 1998	Applicable fees	Applicable Regulatory Framework	Doc Issued
1	submission received before July 8, 1998, but not yet screened	-Part V -old fees -New Fees- Licence Application Fee ($100)	Part V	At completion of Part V review, section 21(1) requirements must be submitted and a licence will be issued.
2	Submission in screening	-Part V-old fees (initial $500 has already been paid) -New Fees- Licence Application Fee ($100)	Part V	At completion of Part V review, section 21(1) requirements must be submitted and a licence will be issued.
3	Submission under review	-Part V -old fees (which have already been paid) -New Fees- Licence Application Fee ($100)	Part V	At completion of Part V review, section 21(1) requirements must be submitted and a licence will be issued.
4	Investigational studies underway (following application for NOC or SNOC)	-Part V -old fees (which have already been paid) -New Fees- Licence Application Fee ($100)	Part V	At completion of Part V review, section 21(1) requirements must be submitted and a licence will be issued.
5	Device has been notified (Part II old regulations)	New Medical Device Fees	New Medical Device Regulations (grandfather clause and grace period to apply)	Device Licence

6	Device has an NOC (Part V old regulations)	New Medical Device Fees	New Medical Device Regulations (grandfather clause and grace period to apply)	Device Licence
7	A marketed device that is subject to Part V of the old regulations where the manufacturer does not have a Notice of Compliance, but the manufacturer has met, after October 8, 1982, and before April 1, 1983, the requirements for device notification pursuant to Part II of the old regulations in respect of the device.	New Medical Device Fees	New Medical Device Regulations (grandfather clause and grace period to apply)	Device Licence

How to Calculate Class III and Class IV Fees

Non-*IVDD*		Component fees (CDNS)				
Item	**Submission Component**	**Device Class**	**New Hip Stem**	**Coronary Vascular Stent (sig. change) same stent for peripheral use**	**New Vascular Graft**	**New Biological Skin Replace-ment Device**
1	materials/intended use/market history	IV		$140	$140	$140
2	risk assessment	IV		$1,000	$1,000	$1,000
3	device specifications	IV			$680	$680
4	production process specifications	IV			$510	$510
5	quality assurance procedures and specs.	IV			$850	$850
6	preclinical and clinical studies (non-IVDD)	IV		$7,670	$7,670	$7,670
7	preclinical and clinical studies (IVDD)	IV				
8	process validation studies	IV			$850	$850
9	software validation studies	IV				
10	labelling	IV		$170	$170	$170
11	biologically sourced component	IV				$2,620
12	near patient testing	IV				
13	materials/intended use/market history	III	$140			
14	safety and effectiveness studies	III	$1,470			
15	labelling	III	$170			
16	near patient testing	III				
17	licensing devices already notified	all				
18	initial licensing for new devices	all	$200		$200	$200
TOTAL			$1,980	$8,980	$12,070	$14,690

Non-*IVDD*		Component fees (CDNS)			
Item	**Submission Component**	**device Class**	**New Hip (Coated and Non-Coated Stem) System***		
			Hip Stem metal, non coated, cemented	**Hip Stem Hydroxyl Apatite coated**	**Acetabular metal cup with plastic liner**
1	materials/intended use/market history	IV			
2	risk assessment	IV			
3	device specifications	IV			
4	production process specifications	IV			
5	quality assurance procedures and specs.	IV			
6	preclinical and clinical studies (non-IVDD)	IV			
7	preclinical and clinical studies (IVDD)	IV			
8	process validation studies	IV			
9	software validation studies	IV			
10	labelling	IV			
11	biologically sourced component	IV			
12	near patient testing	IV			
13	materials/intended use/market history	III	$140	$140	$140
14	safety and effectiveness studies	III	$1,470	$1,470	$1,470
15	labelling	III	$170	$170	$170
16	near patient testing	III			
	SUBTOTAL - PREMARKET REVIEW		$1,780	$1,780	$1,780
18	initial licensing for new devices	all	$200		
	TOTAL - LICENSE APPLICATION		$5,540		

* Total Hip Replacement System. The device is sold under a single system device name (tradename). This stem is available as a cemented non-coated metal, and a mineral (HA) coated stem. All the stems articulate with the same acetabular cup.

Non-*IVDD*		Component fees (CDNS)			
Item	**Submission Component**	**Device Class**	**New Implantable Defibrillator System****		
			Pulse Generator and Programmer with Software	**Superior Vena Cava Electrode lead**	**Multi-polar Electrode Lead**
1	materials/intended use/market history	IV	$140	$140	$140
2	risk assessment	IV	$1,000	$1,000	$1,000
3	device specifications	IV	$680	$680	$680
4	production process specifications	IV	$510	$510	$510
5	quality assurance procedures and specs.	IV	$850		
6	preclinical and clinical studies (non-IVDD)	IV	$7,670		
7	preclinical and clinical studies (IVDD)	IV			
8	process validation studies	IV	$850	$850	$850
9	software validation studies	IV	$2,020		
10	labelling	IV	$170	$170	$170
11	biologically sourced component	IV			
12	near patient testing	IV			
13	materials/intended use/market history	III			
14	safety and effectiveness studies	III			
15	labelling	III			
16	near patient testing	III			
	SUBTOTAL - PREMARKET REVIEW		$13,890	$3,350	$3,350
18	initial licensing for new devices	all	$200		
	TOTAL		$20,790		

** Implantable Cardiac Defibrillator System. This is system is sold under a single device system name (trade name). Included are two electrode lead configurations: multipolar lead which senses and delivers a shock, and the superior vena cava lead. The review for other configurations of leads in such would require separate reviews for each additional lead as outlined above.

Non-*IVDD*		Component fees (CDN$)		
Item	**Submission Component**	**device Class**	**Significant change**	
			Hip Stem System- change in the stem material composition	**Bioprosthetic Heart Valve- change in sewing ring and introducer**
1	materials/intended use/market history	IV		$140
2	risk assessment	IV		$1,000
3	device specifications	IV		$680
4	production process specifications	IV		$510
5	quality assurance procedures and specs.	IV		$850
6	preclinical and clinical studies(non-IVDD)	IV		$7,670
7	preclinical and clinical studies (IVDD)	IV		
8	process validation studies	IV		$850
9	software validation studies	IV		
10	labelling	IV		$170
11	biologically sourced component	IV		
12	near patient testing	IV		
13	materials/intended use/market history	III	$140	
14	safety and effectiveness studies	III	$1,470	
15	labelling	III	$170	
16	near patient testing	III		
SUBTOTAL - PREMARKET REVIEW			$1,780	$11,870
18	initial licensing for new devices	all		
TOTAL			$1,780	$11,870

IVDD			Component fees (CDNS)			
Item	**Submission Component**	**device Class**	**new HCV EIA diagnostic assay**	**NPT-HIV test kit[A] significant change**	**rubella test kit**	**NPT-glucose meter**
1	materials/intended use/market history	IV	$140	$140		
2	risk assessment	IV	$1,000			
3	device specifications	IV	$680			
4	production process specifications	IV	$510			
5	quality assurance procedures and specs.	IV	$850			
6	preclinical and clinical studies (non-IVDD)	IV				
7	preclinical and clinical studies (IVDD)	IV	$5,970			
8	process validation studies	IV	$850			
9	software validation studies	IV				
10	labelling	IV	$170	$170		
11	biologically sourced component	IV				
12	near patient testing	IV		$2,410		
13	materials/intended use/market history	III			$140	$140
14	safety and effectiveness studies	III			$1,470	$1,470
15	labelling	III			$170	$170
16	near patient testing	III				$440
SUBTOTAL - PREMARKET SCIENTIFIC REVIEW			$10,170	2720	$1,780	$2,220
18	initial licensing for new devices	all	$200		$200	$200
TOTAL - LICENSE APPLICATION			$10,370	$2,720	$1,980	$2,420

[A] Rapid test kit with a licence for laboratory use only. The license application is for the same test kit to be marketed for professional use, i.e. as a near-patient (NPT) IVDD.

IVDD			Component fees (CDNS)		
Item	**Submission Component**	**device Class**	**HIV saliva testing system[A]**		
			collection device	**EIA assay**	**WB assay**
1	materials/intended use/market history	IV	$140	$140	$140
2	risk assessment	IV		$1,000	
3	device specifications	IV		$680	
4	production process specifications	IV		$510	
5	quality assurance procedures and specs.	IV		$850	
6	preclinical and clinical studies (non-IVDD)	IV			
7	preclinical and clinical studies (IVDD)	IV		$5,970	$5,970
8	process validation studies	IV		$850	$850
9	software validation studies	IV			
10	labelling	IV	$170	$170	$170
11	biologically sourced component	IV			
12	near patient testing	IV	$2,410		
13	materials/intended use/market history	III			
14	safety and effectiveness studies	III			
15	labelling	III			
16	near patient testing	III			
SUBTOTAL - PREMARKET SCIENTIFIC REVIEW			$2,720	$10,170	$7,130
18	initial licensing for new devices	all	$200		
TOTAL - LICENSE APPLICATION			$20,220		

[A] HIV testing system for saliva. The collection device contains different chemicals to help in the collection of the specimen and for the preservation of the specimen and is sold to health professionals (near-patient testing). All scientific issues regarding the stability of the collected samples would be evaluated under the preclinical and clinical studies of the EIA assay. This approach is consistent with our current approach where the review of data to substantiate the recommended method of sample collection and storage conditions for test kits using plasma or serum is done as part of the preclinical data for the test kit itself. The first-line EIA assay is a new test kit. For the Western Blot assay it is a significant change since it already has a licence for use with serum or plasma. The system is sold under a single tradename. The EIA and WB test kits are sold to testing laboratories.

IVDD			Component fees (CDN$)	
Item	**Submission Component**	**device Class**	**new test kit for donor screening (with automated analyzer)**	
			test kit	**analyzer-software**
1	materials/intended use/market history	IV	$140	$140
2	risk assessment	IV	$1,000	$1,000
3	device specifications	IV	$680	$680
4	production process specifications	IV	$510	
5	quality assurance procedures and specs.	IV	$850	$850
6	preclinical and clinical studies (non-IVDD)	IV		
7	preclinical and clinical studies (IVDD)	IV	$5,970	
8	process validation studies	IV	$850	
9	software validation studies	IV		$2,020
10	labelling	IV	$170	$170
11	biologically sourced component	IV		
12	near patient testing	IV		
13	materials/intended use/market history	III		
14	safety and effectiveness studies	III		
15	labelling	III		
16	near patient testing	III		
SUBTOTAL - PREMARKET SCIENTIFIC REVIEW			$10,170	$4,860
18	initial licensing for new devices	all	$200	
TOTAL - LICENSE APPLICATION			$15,230	

IVDD			Component fees (CDNS)	
Item	**Submission Component**	**device Class**	**significant change to automated PSA[A] test kits (free and total) for diagnosis of cancer**	
			total PSA	**free PSA**
1	materials/intended use/market history	IV		
2	risk assessment	IV		
3	device specifications	IV		
4	production process specifications	IV		
5	quality assurance procedures and specs.	IV		
6	preclinical and clinical studies(non-IVDD)	IV		
7	preclinical and clinical studies (IVDD)	IV		
8	process validation studies	IV		
9	software validation studies	IV		
10	labelling	IV		
11	biologically sourced component	IV		
12	near patient testing	IV		
13	materials/intended use/market history	III	$140	$140
14	safety and effectiveness studies	III	$1,470	$1,470
15	labelling	III	$170	$170
16	near patient testing	III		
SUBTOTAL - PREMARKET SCIENTIFIC REVIEW			$1,780	$1,780
18	initial licensing for new devices	all		
TOTAL - LICENSE APPLICATION			$1,780	$1,780

[A] PSA - Prostate Specific Antigen

IMPACT DISCUSSION PAPER

Description

It is Government policy to implement user charges for services that provide identifiable recipients with direct benefits beyond those received by the general public. The *Financial Administration Act* confers the authority to implement this cost recovery initiative. The fees have been developed within the framework of the Treasury Board Policy entitled *Cost Recovery and Charging Policy (April 1997)*.

The objectives of cost recovery are to shift the cost of government activities which benefit specific individuals or firms from the taxpayer in general to those who benefit most directly from these activities. It is also intended to promote more business-like and equitable management of government programs and facilitate improvements in the delivery of specific cost-recovered services.

The purpose of the proposed *Regulations* is to revoke the current fees Regulations for medical devices and prescribe new client fees for:

- the service provided by the Therapeutic Products Programme (TPP) for the examination of an application for a medical device licence,
- the right or privilege to import or sell a medical device in Canada conferred by granting a medical device licence to manufacturers of class II, III and IV medical devices, and
- the right or privilege to import or sell a medical device in Canada conferred by granting an establishment licence to importers and distributors of class I, II, III and IV medical devices and to manufacturers of class I medical devices who do not have a Canadian importer or distributor.

In February 1991, a review of the medical devices regulatory program was initiated when the former Minister of National Health and Welfare established the Medical Devices Review (Hearn) Committee to formulate recommendations concerning the regulation of medical devices and associated activities. This Committee was established in recognition of the increased volume and complexity of new medical devices used in health care and the need for timely availability of safe and effective devices in the next century.

The report of the Hearn Committee was released in August 1992 and received endorsement of all stakeholders. It recommended a revised approach to regulating medical devices based on the principles of risk assessment and risk management. The Hearn Committee also recommended "the considered development through appropriate consultation with stakeholders, of a cost recovery system applied selectively to defray, in part, the cost of operating an improved medical devices regulatory programme".

The Medical Devices Bureau of Health Canada, now part of the Therapeutic Products Programme (TPP), completed Phase I of its cost recovery initiative by implementing the *Medical Devices Fees Regulations* on January 1, 1996. In Phase I, client fees were applied to medical devices subject to a pre-market evaluation as required under Part V of the current *Medical Devices Regulations*.

The proposed *Fees to be Paid in Respect of Medical Devices Regulations* constitute the second phase of the medical devices cost recovery initiative. Client fees will be charged for an expanded pre-market review program and a number of additional services that will be provided by the TPP as the result of proposed changes to the *Medical Devices Regulations*. The *Medical Devices Regulations* set out a system for classifying medical devices into one of four classes, class I representing the lowest risk devices (e.g. surgical instruments) and class IV representing the highest risk devices (e.g. test kit used for the detection of infectious agents such as Human Immune Deficiency Virus (HIV) and hepatitis viruses). These Regulations, which have been under development since 1992, were published in the *Canada Gazette*, Part I on February 15, 1997 and are targeted to come into effect on July 1, 1998. The introduction of these fees was delayed until Phase II to allow for the implementation of the new *Medical Devices Regulations*.

The total cost of the direct and indirect activities related to the examination of applications for medical device licences and licensing of medical devices and establishments under the new *Medical Devices Regulations* is estimated to be in excess of $12 million. The revenue from the three fee initiatives is expected to recover $7.7 million when fully implemented. The remaining costs will continue to be paid through Appropriations.

The proposed *Fees to be Paid in Respect of Medical Devices Regulations* will establish fees for services based on the requirements

set out in the new *Medical Devices Regulations* and will replace the existing *Medical Devices Fees Regulations*.

Devices which are:

- custom-made;
- imported or sold under the special access program (emergency use);
- imported or sold for investigational testing; or
- which fall into class I,

are not subject to the medical devices licensing requirements under the proposed framework and are exempted from the medical device licensing fees.

These devices have been exempted because of the low risk to the Canadian consumers in the case of class I medical devices and for public good reasons with respect to custom-made medical devices, medical devices sold under the special access program or for investigational testing.

The following establishments are not subject to the establishment licensing requirements under the proposed framework and are exempted from the establishment licensing fees:

- retailers,
- health care facilities, or
- manufacturers of class II, III or IV medical devices.

While manufacturers of class I medical devices are not subject to the medical device product licensing requirements and medical device licensing fees, they are subject to the establishment licensing requirements and establishment licensing fees, if they do not have a Canadian importer or distributor.

I. Fees for Examination of Applications for Medical Device Licences

The proposed fee structure is based on the medical device licensing requirements of the new regulatory framework. Under the new framework, manufacturers must hold a medical device licence to import or sell a class II, III or IV medical device in Canada. Manufacturers of medical devices will be required to submit evidence to support safety and to indicate that effectiveness requirements have been met. The degree of information which must be submitted to provide assurance to the TPP that the safety and effectiveness requirements have been met is proportional to the class of the device. For example, Class IV devices require more information to be submitted than class III devices; class III devices require more information to be submitted than class II devices.

The overall fee to be paid for the examination of a class III or IV medical device application is based on the component fees for the review of the information that must be included in a class III and IV medical device licence application. This will allow a wide range of fees to accommodate the different types of licence applications. This approach, similar in concept to that used for the *Drug Evaluation Fees Regulations*, is intended to ensure that costs are allocated fairly.

The fees are based on average costs to conduct an examination of information which must be included in common components of an application.

The fee for each data component detailed in the proposed Regulations includes both a screening fee and an examination fee. Screening is a service which determines whether the information is complete and in an acceptable form for review.

If an application for a class III medical device licence is preceded by an application for authorization to conduct an investigational testing, the following data component of the fee schedule will not apply:

- description of the medical device and the materials used in its construction and packaging, intended use and a summary of the reported problems with the medical device in other countries.

If an application for a class IV medical device licence is preceded by an application for authorization to conduct an investigational testing, the following data components of the fee schedule will not apply:

- description of the medical device and the materials used in its construction and packaging, intended use and a summary of the

reported problems with the medical device in other countries, and

- risk assessment and risk reduction measures.

The TPP believes that this approach ensures that fees are not charged for work conducted under the previous authorization but also will encourage research and development of new technologies in Canada.

Medical Device Licence Amendment

There will be no fee for class II medical device licence amendments.

If a manufacturer makes a change respecting the application requirements for a class III or IV medical device, the fee payable is for screening and examining each amended data component contained in the application for amendment. In order to decrease administrative burden, there are no separate fees for administrative licence amendments. The cost of this activity will be captured by the annual product licence renewal fee.

Payment of fees

To minimize administrative costs, if the fee payable is $5,000 or less the full fee is payable at the time the application is submitted. For all applications, the portion of the fee related to screening is payable whether or not the application is accepted for review.

Fee Reduction Provisions

As with other TPP cost recovery activities, provision is made for reduced fees to prevent severe financial burden to small businesses and to minimize impact to product availability by promoting the continued introduction of low volume or low sales medical devices. Three separate fee reduction provisions are proposed. The fee reduction provisions apply to initial product licensing and annual product licensing renewal fees and as an overall cap on the annual product licence renewal fees. The fees reduction provision will limit the initial product licensing fee to 5% of the applicant's actual gross revenue from sales in Canada of the medical device during a two year period beginning on the date that the medical device is first sold in Canada.

Appeal Process

There will be a formal appeal process to facilitate the resolution of contentious cost recovery issues. The appeal process will follow the existing two level appeal process model utilized for regulatory and cost recovery activities in TPP. The appeal process will be made available with the Medical Devices Fees guidance documents.

Transition

Applications for the issuance of a Notice of Compliance pursuant to Part V of the current *Medical Devices Regulations* received prior to July 1, 1998 will be subject to the current *Medical Devices Fees Regulations*. Applications for the issuance of a Notice of Compliance pursuant to Part V of the current Regulations received after July 1, 1998 will be subject to the proposed new *Fees to be Paid in Respect of Medical Devices Regulations*.

Manufacturers of devices which are being sold in Canada when the new *Medical Devices Regulations* take effect will be provided a grace period to license those devices. The grace period will end on February 1, 1999, meaning that the devices must be licensed by that date. A single fee of $110 will be charged for an application in respect of a medical device that on June 30, 1998 is being sold in Canada pursuant to the current Regulations in the following cases:

- a device that is subject to Part V of the current Regulations, the manufacturer of which has been issued a Notice of Compliance on or before June 30, 1998,or
- a device that is not subject to Part V of the current Regulations, the manufacturer of which has met the requirements for a device notification pursuant to Part II of the current Regulations on or before June 30, 1998. Manufacturers of medical devices subject to

Part II of the current Regulations are required to notify the TPP that they are selling the product in Canada, within 10 days of first sale, and must possess evidence of the product's safety, quality and effectiveness.

An application for the issuance of a Notice of Compliance pursuant to Part V of the current Regulations that is under review by the Minister when the new Regulations come into effect will be processed as if that Part were still in force. A single fee of $110 will be charged to license those devices.

II. Annual Medical Device Licensing Fees

An annual fee for the right or privilege to sell a medical device in Canada will be charged to the licensees for each medical device sold in Canada. Fees will be charged at the time of the annual licence renewal in respect of the twelve month period commencing on November 1st, in the year in which the fee is required to be paid.

The fee collected for this right or privilege will be used to pay for the activities performed by the TPP that relate to the administration of medical device licensing. These activities include a portion of the post-market activities which are product related.

To reduce the impact on small manufacturers, a fee reduction provision has been proposed whereby low sales volume products are subject to a lower fee of $50 when the gross revenue of that medical device is $20,000 or less, during the licensee's previous fiscal year, based on certified financial records. In addition to the product specific fee reduction provision, there is an overall cap on the annual product licence renewal fees. The cap will limit the overall cost of annual fees to 1.5% of total sales of the firm.

III. Establishment Licensing Fees

The proposed establishment licensing fees are based on the requirements in the new medical devices regulatory framework.The fee to be paid is for the right or privilege to import or sell a medical device conferred by granting an establishment licence to importers or distributors of class I, II, III or IV medical devices and to manufacturers of class I medical devices who do not have a Canadian importer or distributor.

A fee will be charged for each establishment in the case of an initial establishment licence application. An annual fee will be charged for the renewal of each establishment licence. The fee collected for the right or privilege to hold an establishment licence will be used to pay for the activities performed by the TPP that relate to the administration of establishment licensing. These include a portion of the post-market activities which are establishment related. The establishment licensing fee will be charged annually in respect of the twelve month period commencing on January 1st, in the year in which the fee is required to be paid.

Establishments engaged in the activities of distribution or importation and certain class I manufacturing establishments are subject to establishment licensing and therefore the fees. TPP is working with industry to develop guidance on this issue.

Reinstatement of Licence

The full fee will be charged for the reinstatement of a medical device licence or an establishment licence that had been suspended.

Review

The final phase of the cost recovery implementation plan is the 1999 Phase IV review of all TPP cost recovery initiatives to determine the overall impact of cost recovery on different sectors of the drug and medical device industries and on the Canadian public. The TPP is currently defining the scope and approach to the review. As a result of this review, the existing fee Regulations will be examined to address issues identified. The review will also ensure that the TPP is consistent withTreasury Board's policy entitled *Cost Recovery and Charging Policy (April 1997).*

The proposed regulatory framework, as published in *Canada Gazette*, Part I in February 1997, is consistent with regulatory frameworks for medical devices in the European Union, the United States, and Australia. The implementation of harmonized regulatory requirements has provided the opportunity to begin the negotatiation of Mutual Recognition Agreements (MRAs) with Canada's trading partners. MRAs are beneficial to industry and in the long term will result in regulatory efficiencies.

International Comparisons

Similar to the Therapeutic Goods Administration (TGA) in Australia, the Centre for Devices and Radiological Health (CDRH) in the United States and the Medical Devices Division of the National Institute of Health Sciences (NIHS) in Japan, the TPP's mandate is to ensure that the medical devices available in Canada are safe, effective and of high quality. Australia and Japan, two of Canada's major trading partners, recover fees for medical devices regulatory activities.

In Australia, fees and charges are payable for the registration and listing of therapeutic devices, the licensing of therapeutic goods manufacturers, and other activities controlled under the *Therapeutic Goods Act, 1989.*

In the United States, fees for medical devices regulatory activities are not in place.

The European Union (EU) system is designed not only to ensure that devices are safe and effective but also to facilitate EU-wide trade by creating a single review process that permits devices to be marketed in all Members States. Under the EU system both governmental and private organizations review and approve medium and high risk devices. These are referred to as notified bodies and are privately owned and operated firms. Manufacturers pay fees to the notified body of their choice to conduct assessments of devices they would like to market.

A comparison of proposed Canadian fees and performance standards to those of the CDRH in the United States, the TGA in Australia, the NIHS in Japan and the EU are illustrated in the following table.

Jurisdiction	Fees ($Canadian)	Performance standards
TPP (Canada) current fees	$125 - $11,000	60 calendar days
TPP (Canada) proposed fees	$200 - $15,000	15 to 60 calendar days
CDRH (USA)	nothing in place	16 months[1]
TGA (Australia)	$220 - $35,000	120 working days
NIHS (Japan)	$175 - $7,900	unable to obtain
EU	$8,000 third party contracts design dossier review	~ 90 calendar days

[1] *New Directions in Medical Device Regulation - An FDA Progress Report, 1997.*

Canada's existing and proposed performance standards are the lowest in the world.

Performance Standards

This cost recovery initiative will ensure that the Canadian medical device regulatory program will meet standards of efficiency and service that industry and the Canadian public have been demanding and that were recommended in the Hearn report and the subsequent review of the report's recommendations.

With respect to the pre-market scrutiny of scientific/technical data, the TPP will undertake an increased workload. The current five to ten percent of medical devices which undergo scientific/technical scrutiny will increase to twenty percent. For approximately three quarters of these devices (class III), the TPP will review summarized safety and effectiveness information. For the remainder (class IV), a detailed review of data will be required as is currently done.

Since 1995, the TPP has consistently met performance standards acceptable to industry for reviews of applications for the issuance of a Notice of Compliance pursuant to Part V of the current Regulations. The TPP is confident that reviews conducted with this increased workload will continue to be done within acceptable time frames if adequate resources are available. Performance standards will be consulted with the medical devices industry, implemented and performance will be measured against these standards. The TPP is committed to develop and fully meet future performance standards which are internationally competitive with the best in the world, while maintaining its high quality standards.

Alternatives

Cost recovery is government policy. The activities carried out by the TPP meet the criteria for charging appropriate rates for the services, rights or privileges afforded the medical device industry which directly benefit from these services. Client fees are consistent with the Government's objective of promoting more business-like, consistent and equitable management of the TPP.

The 1994 Programme Review resulted in a decision to reduce Appropriations for medical devices regulation by $5.8 million in anticipation of cost recovery. Failure to raise revenue to replace these Appropriations to pay for the activities required under the new *Medical Devices Regulations* will make it impossible for the TPP to maintain an adequate regulatory program for medical devices. Canadians expect medical devices to be safe and effective. To maintain a high level of confidence in the safety and effectiveness of medical devices, this cost recovery initiative is considered the only acceptable alternative.

Any acceptable alternative must result in the collection of approximately $7.7 million to support the recommended levels of service and establish efficiencies under the revised proposed *Medical Devices Regulations*. Stakeholders were invited to propose alternatives to the proposed fee structure, including areas where exemptions or reductions might be appropriate.

The proposed fee schedule reflects consultation with stakeholders over the past six months. This document also addresses the concerns expressed by stakeholders during the August consultation workshop and from the analysis of the business impact assessment conducted on this initiative. The majority of these concerns have been addressed through changes to improve the regulatory framework and through improvements to the fee proposal originally presented in August 1997.

The TPP has introduced or is exploring a number of options which will cut program costs and introduce new efficiencies. These include, but are not limited to, harmonization of regulatory requirements, the development of mutual recognition agreements with other regulatory authorities, the implementation of quality system requirements whereby audits would be conducted on behalf of the TPP by independent third party audit organizations and electronic exchange of information between the manufacturers and the TPP. The TPP is also pursuing an approach similar to the TGA in Australia whereby certain lower risk class I products are exempted from any registration requirements. All of these efforts will enable the TPP to keep the fees at a level which, while providing an appropriate safety assurance to the public, are not economically prohibitive.

Benefits and Costs

This initiative will impact on the following:

Industry

This initiative is expected to directly impact on approximately 1,000 firms producing medical/surgical supplies, diagnostics, implants, hospital equipment and assistive devices. A business impact assessment, equivalent to a Business Impact Test (BIT), was undertaken to assess the impact. The report entitled *"Business Impact Assessment of the Proposed Fee Schedule for Medical Devices Sold in Canada"* was posted on the Web site in early January 1998. The consultation section of this document provides a summary of the issues identified and the adjustments made to the fee schedule to reduce the impact on the industry.

The funds derived from cost recovery will enable the reform of the medical devices regulatory system recommended in the Hearn report in August 1992 to proceed. Reform to the medical devices regulatory system will enhance the safety and effectiveness of medical devices, as well as public confidence in the regulatory system. An efficient medical devices regulatory process will ensure timely market entry for new medical devices, translating into a significant financial benefit to the industry.

Some benefits to medical device manufacturers, importers and distributors include:

- enhanced confidence amongst Canadians in the safety and effectiveness of medical devices that may well translate into expanded markets;

- reduced costs to industry due to reduced liability;

- international recognition of high and credible Canadian standards, which will provide additional international trade opportunities; and

- assistance and advice from the TPP's scientific professional.

While the fees will have an impact on the industry in terms of increased business costs, the benefit will be an efficient, streamlined and effective medical devices review process. This will result in the medical devices industry having timely access to market which increases overall revenue potential.

Consumers

Canadians must have confidence in the regulatory measures undertaken by the TPP to provide safe and effective medical devices.

A portion of the fees are likely to be passed on by medical devices firms to users in the form of higher prices. The total Canadian wholesale sales of medical devices in 1996 was estimated to have been over $2.6 billion. The $7.7 million which is expected to be recovered therefore, represents less than 0.3% of Canadian wholesale sales. Furthermore, most devices are not paid for by consumers - there is a fairly small cash market. This market characteristic should further reduce the potential for increased direct consumer costs.

The business impact assessment was conducted to assess anticipated effect of the proposed fees. While the impact of the fees for the examination of applications for medical device licences will not affect firms uniformly, overall the impact of the proposed fees on the price of medical devices is predicted to be acceptable

due to the proposed fee reduction provisions which limit the total product fees charged to any firm to a maximum of 1.5%.

The collection of fees will ensure that the Canadian public continues to benefit from the availability of safe and effective medical devices assessed in a timely fashion, while paying less through taxes for this program.

Provinces and Health Care Institutions

The major purchasers of medical devices are the provinces and their health care institutions. Thus, they can expect to face the majority of cost increases. However, health care expenditures in Canada in 1996 exceeded $75 billion while sales of medical devices totalled approximately $2.6 billion (about 2% of the total health care budget). The costs associated with this cost recovery initiative totals $6.5 million or less than 0.5% of total expenditures on medical devices in Canada. A portion of these increased costs will be passed through to consumers and health care institutions. However, any increase in costs is expected to be small.

At the same time, however, the business impact assessment suggested that without the benefit of fee reduction provisions, two-thirds of devices that remain on the market could experience an average price increase of roughly 5%. The extent to which such price increases can be passed on to the health care system is unknown at this time, but this may pose a challenge to health care facilities operating within ever tightening budgets. It has been suggested that facilities will respond by delaying purchases, extending use of existing device technology and reusing devices. While this result might have negative consequences for the quality of health care and the potential risk posed to patients it is not expected to be a widespread occurrence. This aspect will be examined in Phase IV of the TPP cost recovery initiative when real evidence of impact can be collected.

Business decisions may reduce the total number of devices on the market but there will be no impact on availability of needed devices.

Therapeutic Products Programme

In accordance with the Government's *Cost Recovery and Charging Policy*, the TPP is expected to recover a portion of its costs through the implementation of client fees for services that provide identifiable recipients with direct benefits beyond those received by the general public. To ensure that the current and planned TPP activities for medical devices are efficient and effective, the TPP determined that approximately $7.7 million must be raised through fees.

The total costs associated with medical device regulatory activities in fiscal year 1998-99 will be in excess of $12 million. The implementation of client fees will enable the TPP to maintain program delivery while the cost of the financial system (e.g. accounts receivable system) to support this initiative was covered at the time of implementation of Phase I of the medical devices cost recovery initiative.

Consultation

Early notice of this regulatory initiative was provided by entry No. HCan/97-13-M of the 1997 *Federal Regulatory Plan.*

Consultations on client fees began during the deliberations on the Medical Devices Review (Hearn) Committee in 1991-92 and specifically with the publication of Health Protection Branch Information Letters No. 811 and 812.

The report of the Hearn Committee, which was released in August 1992 and which received endorsement of all stakeholders, recommended "the considered development, through appropriate consultations with stakeholders, of a cost recovery system applied selectively to defray, in part, the cost of operating an improved medical devices regulatory programme".

The Medical Devices Bureau completed Phase I of its cost recovery initiative by implementing the *Medical Devices Fees Regulations* on January 1, 1996. In Phase I, client fees were applied to medical devices subject to Part V of the current *Medical Devices Regulations*.

The proposed *Fees to be Paid in Respect of Medical Devices Regulations* constitute the second phase of the medical devices cost recovery initiative.

Consultation on fees for activities under the proposed *Medical Devices Regulations* started with a consultation workshop held by the TPP from August 24 to 26, 1997, with a wide range of industry, provincial government, consumer and health professional stakeholders. Discussions focussed on the acceptability of the proposed fee structure, performance standards, the need for a fee reduction provision and for adequate guidance documents. While industry generally accepts cost recovery and the proposed fee structure in principle, there was concern about the potential impact of fees on company profits of lower sale products on the Canadian market. Preliminary results of the business impact assessment were presented which indicated that the total cost of the TPP, and revenue expected, each represented a lower percentage of total industry sales than similar values for other Health Canada regulatory programs. The proposed fees are proportionally less than fees charged for other regulatory activities at Health Canada. This indicates that the revenue expectations are not unreasonable.

A second consultation workshop was held in October 1997 with a cross section of small businesses to explore mechanisms to mitigate the effect of fees on small business.

On October 15-16, 1997, the TPP met with 15 stakeholders representing various sectors of the medical devices industry to further refine the interpretation of a medical device for licensing purposes which impacts on the application of fees.

Three information sessions were held with the medical devices industry in November and December 1997 to discuss the proposed *Medical Devices Regulations* published in *Canada Gazette*, Part I on February 15, 1997 and the proposed cost recovery initiative. The TPP met with the Medical Devices Canada (MEDEC) industry association in September 1997 and January 1998 to discuss further the proposed cost recovery initiative.

A business impact assessment, equivalent to a Business Impact Test (BIT), was undertaken to assess the anticipated effect of the proposed fees. The report entitled *"Business Impact Assessment of the Proposed Fee Schedule for Medical Devices Sold in Canada"* was posted on the TPP Web site in early January 1998.

Concerns related to the proposed medical devices fees were identified in the comments received following the prepublication of the proposed *Medical Devices Regulations* in the *Canada Gazette*, Part I on February 15, 1997, by the business impact assessment and in comments received from firms and medical device associations following the TPP/industry consultation workshop in August 1997. A summary of the issues identified and the TPP response is provided below:

1. Concern was raised by respondents of the business impact assessment.For small companies with total annual sales of less than $5 million, the proposed client fees were predicted to impose costs representing 7.7% or more of total sales. In contrast, for firms with sales in excess of $5 million the client fees will represent less than 1% of sales. The proposed client fees were therefore deemed to be inconsequential to larger firms and punitive for smaller businesses.

   Response: The business impact assessement did not include any consideration of fee reduction provisions. The TPP is proposing fee reduction provisions to mitigate the effect of fees on small businesses. Three separate fee reduction provisions are proposed. The fee reduction provisions apply to initial product licensing and annual product licensing renewal fees and as an overall cap on the annual product licence renewal fees. The fees reduction provision will limit the initial product licensing fee to 5% of the applicant's actual gross revenue from sales in Canada of the medical device during a two year period beginning on the date that the medical device is first sold in Canada. To reduce the impact on small manufacturers and low sales volume products, a minimum $50 fee for the medical device licence renewal will be charged when the value of the annual wholesale sales of the device is less than $20,000. In addition to the product specific fee reduction provision, there is an overall cap on the annual product licence renewal fees. The cap will limit the overall cost of annual product licence fees to 1.5% of total sales of the firm.

   The business impact assessement also did not account for changes made to the proposed *Medical Devices Regulations* to introduce efficiencies to the TPP. For example, the TPP has modified the requirements for class I medical device manufacturers. Manufacturers of class I medical devices will not be subject to the device licensing requirements under the proposed framework.

   Medical devices which are not subject to the product licensing requirements under the proposed framework are exempted from the medical devices licensing fees. These are medical devices which are: custom-made, to be imported or sold under the special access program (emergency use), imported or sold for investigational testing, or class I.

   In addition, the medical devices framework brings a number of types of establishments (retailers, health care facilities and manufacturers of class II, III or IV medical devices) outside the scope of the framework, and therefore, exempts these establishments from fees.

2. Stakeholders expressed concern about the high level of fees, specifically for medical device licensing renewal fees for low sales products and fees for the examination of an application for the licensing of an *in vitro* diagnostic device (IVDD).

Response: The annual medical device licensing fee covers the cost of maintenance activities for the product licensing performed by the TPP, which in turn are based on risk management principles.

The examination of an application for the licensing of an IVDD fee is based on average costs to conduct an examination of information which must be included in common components of an application for the licensing of an IVDD. A costing analysis of these activities was done by the TPP to establish charges that reflect the costs of services provided.

3. The possibility of increased fees in the future, especially extension to Class I devices was a concern expressed by stakeholders.

   Response: The TPP has modified the requirements for class I medical device manufacturers. Manufacturers of class I medical devices will not be subject to the device licensing requirements under the proposed framework. Manufacturers of class I devices who do not have a Canadian importer or distributor will be required to hold an establishment licence to sell, and will therefore be subject to establishment licensing fees.

4. Respondents of the business impact assessment indicated that they did not understand how to calculate appropriate fees. This appeared to be related to a combination of two key factors: lack of a clear definition of a device for licensing purposes and lack of clarity on risk classification.

   Response: On October 15-16, 1997, the TPP met with representatives of industry to discuss and clarify the interpretation of a medical device for licensing purposes. The TPP will accept under the same licence, a kit, a system, a single component device, a multi- component systems and a family of devices. Guidance documents on the interpretation of a device for licensing purposes and on risk classification were developed in consultation with stakeholders and are available on the TPP Web site.

5. There is concern about the cumulative effect of fees. A number of the respondents of the business impact assessment pay fees to other federal regulatory programs, including: TPP for human drugs; Pest Management Regulatory Agency (PMRA) for pest control products; Bureau of Veterinary Drugs for veterinary drugs. It was suggested at the small businesses workshop that there should be an overall ceiling on the TPP annual client fees.

   Response: The TPP's policy *Drug/Medical Device Combination Products* addresses industry's concerns about drug/medical device combination products. A review of the fees, including the cumulative effect, will be conducted in Phase IV of the TPP's cost recovery initiative and adjustments will be made accordingly. In the disinfectant area, the TPP is working towards eliminating regulatory overlap with PMRA and duplication of fees was addressed in the *Fees to be Paid in Respect of Pest Control Products*.

6. The proposed amount for administrative changes seems significant given the work involved by the Programme in updating its files. As well, the definition of such a change could result in a significant cost to individual companies.

   Response: In response to this concern, the fee schedule presented at the August 1997 workshop has been

revised. There will be no separate fee for medical device licence amendments which are considered to be administrative amendments. A change in any of the following information is considered to be an administrative amendment:

- the name of the manufacturer,
- the name of the device,
- the medical device identifier, or
- for class II devices, the medical conditions, purposes or uses for which the device is manufactured, sold or represented.

The cost of these activities will be built into the annual product licence renewal fees.

The fee to be paid for an application for a class III or IV medical device licensing amendment will be based on the relevant data components necessary to support the change requested. The manufacturer is required to submit an application for device licensing amendment when proposing to make a change in the information provided for licensing of the device that results in a significant change, or a change that would affect the class of the device. A guidance document on significant changes is being developed and will be available prior to implementation of the proposed *Medical Devices Regulations*. There will be no fee for application for class II device licensing amendments.

7. It has been observed that the current fees for investigational protocols differ for IVDD and non-IVDD devices. Stakeholders stated that the proposed fees will significantly impact their ability to do research and development of new products in Canada.

Response: The regulatory requirements for investigational testing in the proposed new *Medical Devices Regulations* have been simplified to encourage research and development in Canada. Only the essential data will be assessed by the TPP for authorization to conduct investigational testing. Detailed data will be required as part of the application for device licensing in order for the TPP to assess the safety and effectiveness of the device.

Medical devices imported or sold for investigational testing are not subject to the medical device licensing requirements under the proposed framework. Therefore, there will be no fee for applications for authorization to conduct an investigational testing involving medical devices. Furthermore, some of the fee components of the medical device licensing application will not apply if an authorization for sale of a medical device has been granted to a qualified investigator in the circumstances referred to in Part III of the proposed *Medical Devices Regulations*.

8. The Programme should demonstrate clear and genuine attempts at introducing cost-efficiencies or alternatives. Industry should not pay for activities that may be less costly using alternative means. The TPP should increase its efforts to cut costs through international harmonization.

Response: The TPP has introduced or is exploring a number of options which will cut Programme costs and introduce new efficiencies. These include, but are not limited to, harmonization of regulatory requirements, the development of mutual recognition agreements with other regulatory authorities, the

implementation of quality system requirements whereby audits would be conducted on behalf of the TPP by independent third party audit organizations and electronic exchange of information between the manufacturers and the TPP. The TPP is also pursuing an approach similar to the TGA in Australia whereby certain lower risk class I products are exempted from any registration requirements. All of these efforts will enable the TPP to keep the fees at a level which, while providing safety assurance to the public, are not economically prohibitive and are internationally competitive.

9. The schedule for the finalization and implementation of the Mutual Recognition Agreement was questioned.

Response: After three years of negotiation, Canada and the European Community (EC) have initialled a multi-sectoral recognition agreement (MRA) on conformity assessment. The purpose of the MRA on medical devices is to establish mutual recognition of the ability of each Party to perform conformity assessments to the regulatory requirements of the other Party. The Medical Devices Annex of the MRA covers all devices except *in vitro* diagnostic devices, silicone gel-filled breast implants, and devices containing drugs. This agreement is subject to the ratification of the political authorities of both Parties and the endorsement of the European Community member states. It is expected that the MRA will come into force in early 1998. The coming into force will include a transition phase (confidence building exercise) and an operational phase.

The confidence building exercise requires European regulatory authorities and conformity assessment bodies (CABs) to demonstrate a requisite level of proficiency in operating to Canadian regulatory requirements. Only those regulatory authorities and CABs demonstrating the required proficiencies will be recognized as able to certify products for the Canadian market. This exercise will include the exchange of information and a series of joint and comparative activities. At the end of this phase, there will be an opportunity to evaluate the results of these activities and, if satisfactory, to move to the operational phase of the sectoral agreement.

Preliminary MRA discussions have been undertaken with Switzerland, New-Zealand, Australia, Japan, and the European Free Trade Association (EFTA) states (Norway, Iceland and Liechtenstein). Additionally, a "partnering" program is underway with the USA's FDA to exchange information and expertise in the pre-market review of medium to high risk medical devices.

10. Stakeholders believe there is a mix of public versus private benefit associated with the work performed by the TPP. The identity of the main beneficiaries of regulatory scrutiny for medical devices needs to be established.

Response: The objectives of the Treasury Board cost recovery policy are increased fairness in the allocation of costs for government programs. The Treasury Board policy assumed 100% cost recovery and then allows provisions for a reduced amount. The regulatory activities of the TPP are considered to be services which primarily benefit or are caused by industry. As such, it is appropriate for some or all the associated costs to be recoverable through fees. In this specific case about 70% of the total costs of the TPP are being recovered through fees. Appropriations cover the rest including the full cost of some activities considered to be public goods (e.g. special access programme, authorization for investigational

testing).

The consultation process identified opportunities for making the TPP more efficient and cost effective, opportunities for improving the working relationship between the programme and stakeholders, the positive aspects of the proposed fee schedule, the issues and potential impacts of the fee schedule proposals and means of minimizing the negative impacts.

All comments received will be collected until the end of the 30-day comment period provided by this prepublication and will be considered in the development of the final proposal to be published in the *Canada Gazette*, Part II.

FEES TO BE PAID IN RESPECT OF MEDICAL DEVICES REGULATIONS

PART 1
REGISTRATION FEES

Application

Applicable classes

2. This Part applies to medical devices that are referred to in the Regulations, other than in the provisions of Part II or III, and that are classified into one of classes II to IV pursuant to sections 5 and 6 of the Regulations.

Fee to be Paid for the Examination of an Application for Registration of a Class II Medical Device

Class II medical device

3. (1) The fee to be paid by a manufacturer for the examination of an application for registration of a class II medical device is $200.

Time of payment

(2) The fee referred to in subsection (1) is payable at the time the application is submitted.

Fees to be Paid for the Screening and Examination of an Application for Registration of a Class III or IV Medical Device

Class III or IV medical devices

4. (1) Subject to subsection (2), the fee to be paid by a manufacturer for the screening and examination of an application for registration of a class III or IV medical device is $200 plus the following:

(*a*) in the case of a class III medical device, the sum of the applicable fees set out in column 2 of an item of Schedule 1 for the application information components referred to in column 1 of that item; and

(*b*) in the case of a class IV medical device, the sum of the applicable fees set out in column 2 of an item of Schedule 2 for the application information components referred to in column 1 of that item.

Authorization for sale to a qualified investigator

(2) If an authorization for the sale of a medical device to a qualified investigator has been granted in accordance with subsection 62(2) of the Regulations, the fee to be paid by a manufacturer for the screening and examination of an application referred to in subsection (1) in respect of the medical device is $200 plus the following:

(*a*) in the case of a class III medical device, the sum of the applicable fees set out in column 2 of items 2 to 4 of schedule 1 for the application information components referred to in column 1 of those items; and

(*b*) in the case of a Class IV medical device, the sum of the applicable fees set out in column 2 of items 3 to 12 of Schedule 2 for the application information components referred to in column 1 of those items.

Amendment to device registration

5. The fee to be paid by a manufacturer for the screening and examination of an application for amendment that is a significant change to a medical device in accordance with paragraph 24(*a*) of the Regulations in respect of a class III or IV medical device or a change that would effect the class of a medical device in accordance with paragraph 24(*b*) of the Regulations in respect of a medical device that will be classified as a class III or IV medical device, is the following:

(*a*) in the case of a class III medical device, the sum of the applicable fees set out in column 2 of an item of Schedule 1 for the application information components referred to in column 1 of that item that are related to the application for amendment; and

(*b*) in the case of a class IV medical device, the sum of the applicable fees set out in column 2 of an item of Schedule 2 for the application information components referred to in column 1 of that item that are related to the application amendment.

Method of payment — $5,000 or less

6. (1) If the fee payable pursuant to section 4 or 5 or subsection 9(1) is $5,000 or less, the fee is payable at the time the application is submitted.

Screening fee

(2) Despite sections 4 and 5 and subsection 9(1), if an applicant receives a notice from the Minister stating that the application has been screened but has not been accepted for examination, the fee to be paid is

(*a*) 10 per cent of the fee referred to in section 4 or 5, or

(*b*) 10 per cent of the amount referred to in paragraph 9(2)(*a*).

Method of payment — more than $5,000

(3) If the fee payable pursuant to section 4 or 5 or subsection 9(1) is more than $5,000, the fee is payable as follows:

(*a*) 10 per cent on receipt of a notice from the Minister stating that the application has been screened;

(*b*) 65 per cent on receipt of a notice from the Minister stating that the application has been accepted for examination; and

(*c*) 25 per cent on receipt of a notice from the Minister stating that the application has been approved.

Reduction

Application for a reduction

7. (1) At the time a manufacturer submits an application for a registration or for an amendment to registration in respect of a medical device, the manufacturer may apply to the Minister for a reduction in the fee payable under subsection 3(1) or section 4 or 5.

Fee reduction granted

(2) The Minister shall grant an application for a reduction where the Minister has reasonable grounds to believe that the fee calculated in accordance with subsection 3(1) or section 4 or 5 will be more than 5 per cent of applicant's actual gross revenue from sales in Canada of the medical device in respect of which the application relates during the following period:

(*a*) in the case of an application for a registration, a two year period beginning on the date that the medical device is first offered for sale in Canada; and

(*b*) in the case of an application for an amendment to registration, a two year period beginning on the date of issuance, by the Minister, of the amended registration.

Fee payable — class II medical devices

8. (1) Where the Minister grants an application for a reduction in respect of a class II medical device application, the fee payable by the manufacturer for the examination of the application for registration of the device is $100.

Actual gross revenue

(2) Where the fee to be paid in accordance with subsection 3(1) is less than 5 per cent of the applicant's actual gross revenue from sales of the medical device in Canada during the period referred to in paragraph 7(2)(*a*), the fee that is payable is the fee referred to in subsection 3(1).

Time of payment

(3) The fees to be paid in accordance with this section are payable as follows:

(*a*) in the case of the fee referred to in subsection (1), $100 on submission of an application for reduction; and

(*b*) in the case of the fee referred to in subsection (2), an amount equal to the difference between the fee payable under subsection (2) and the fee referred to in paragraph (*a*), upon expiry of the 60 days following the period referred to in paragraph 7(2)(*a*).

Audited sales records

(4) If the Minister determines that information available to the Minister is not adequate to calculate the applicant's actual gross revenue from sales of the medical device in Canada during the period referred to in paragraph 7(2)(*a*), the Minister may require the applicant to submit sales records that have been audited by a qualified independent auditor and those records shall be used for the purpose of determining the fee to be paid.

Fee payable — classes III and IV medical devices

9. (1) Where the Minister grants an application for a reduction in respect of a class III or IV medical device, the fee payable for the screening and examination of an application for registration of that device is the lesser of

(*a*) the fee to be paid in accordance with those sections, and

(*b*) 5 per cent of the applicant's actual gross revenue from sales of the medical device in Canada during the period referred to in paragraph 7(2)(*a*) or (*b*) as applicable, as verified by certified sales records prepared in accordance with generally accepted accounting principals provided by the applicant upon expiry of the period referred to in paragraph 7(2)(*a*) or (*b*).

Time of payment

(2) The fee calculated in accordance with subsection (1) is payable as follows:

(*a*) an amount equal to 5 per cent of the applicant's anticipated gross revenue from sales of the medical device in Canada during the period referred to in paragraph 7(2)(*a*) or (*b*), as applicable, payable by the manufacturer in accordance with subsection 6(1), (2) or (3); and

(*b*) the balance, if any, upon expiry of the 60 days following the period referred to in paragraph 7(2)(*a*) or (*b*).

Remission

(3) If upon expiry of the 60 days following the period referred to in paragraph 7(2)(*a*) or (*b*) the amount payable in accordance with paragraph 2(*a*) is greater than the fee referred to on paragraph 1(*b*), the Minister shall grant a remission to the

applicant of an amount equal to the difference between those amounts.

Audited sales records

10. (1) If the Minister determines, on the basis of any information available to the Minister, that the certified sales records provided in accordance with paragraph 9(1)(*b*) are not adequate to calculate the applicant's gross actual revenue referred to in that paragraph, the Minister may require the applicant to submit sales records that have been audited by a qualified independent auditor.

Discrepancy in sales records

(2) If there is a discrepancy between the applicant's certified sales records referred to in paragraph 9(1)(*b*) and the audited sales records submitted in accordance with subsection (1), the latter shall be used for the purpose of determining the fee payable.

Failure to submit sales records

(3) If, upon expiry of the 60 days following the period referred to in paragraph 7(2)(*a*) or (*b*) an applicant fails to submit to the Minister certified sales records in accordance with paragraph 9(1)(*b*) or audited sales records in accordance with subsection (1), the fee payable is equal to the difference between the fee referred to in section 4 or 5, and the amount referred to in paragraph 9(2)(*a*).

Fee to be Paid for the Right or Privilege to Sell a Medical Device Conferred by Registration

Definition

11. (1) In this section and in section 12 "annual gross revenue" means the gross revenue of the holder of a registration in respect of a medical device, during the holder's previous fiscal year, from sales of the device in Canada.

Amount of fee

(2) The fee to be paid by the holder of a registration, in respect of each medical device registered in the name of the holder, is the following:

(*a*) $100, if the holder's annual gross revenue is $20,000 or more; or

(*b*) $50, if the holder's annual gross revenue is less than $20,000, based on the certified sales records prepared in accordance with generally accepted accounting principles and provided by the holder at the time of payment referred to in subsection (4).

Reduction

(3) Despite subsection (2), if the total amount of fees payable by a person for all medical devices registered in the name of the person is greater than 1.5 per cent of the total annual gross revenue based on certified sales records prepared in accordance with generally accepted accounting principles and provided by the person at the time of payment referred to in subsection (4), the fee that is payable in respect of all medical devices registered in the name of that person is 1.5 per cent of the total annual gross revenue of the person.

Time of payment

(4) The fees referred to in subsections (2) and (3) are payable by the holder of the registration on November 1 of each year in

respect of each medica
that date.

Audited sales records

12. (1) If the Minister determines, on the basis of any information available to the Minister, that the certified sales records provided in accordance with paragraph 11(2)(*b*) or subsection 11(3) are not adequate to calculate the annual gross revenue or total annual gross revenue referred to in those provisions, the Minister may require the applicant to submit sales records that have been audited by a qualified independent auditor.

Discrepancy in sales records

(2) If there is a discrepancy between the applicant's certified sales records referred to in paragraph 11(2)(*b*) or subsection 11(3) and the audited sales records submitted in accordance with subsection (1), the latter shall be used for the purpose of determining the fee payable.

PART 2

ESTABLISHMENT REGISTRATION FEES

Application

Applicable classes

13. This Part applies to medical devices that are subject to the Regulations, other than the provisions of Part II or III, and that are classified into one of classes I to IV pursuant to sections 5 and 6 of the Regulations.

Fee to be Paid for the Right or Privilege to Sell a Medical Device Conferred by Granting of Registration to an Establishment

Amount of fee

14. (1) The fee to be paid for the registration of an establishment pursuant to section 28 of the Regulations is the following:

(*a*) $2,530 for each establishment, for initial registration; and

(*b*) $2,120 for each establishment, for the renewal of a registration.

Date of payment

(2) The fee referred to in subsection (1) is payable on the date of issuance of the establishment registration or renewal of the establishment registration, by the Minister.

PART 3

TRANSITIONAL PROVISIONS, REPEAL AND COMING INTO FORCE

Transitional Provisions

Definition

15. (1) For the purposes of this section, "old Regulations" means the *Medical Devices Regulations*.

Medical devices subject to the old Regulations

(2) Despite these Regulations, the fee to be paid by a manufacturer for the screening and examination of an application for registration submitted in accordance with section 76 or 77 of the Regulations is $110.

Non-application of the old Regulations

(3) The fee referred to in subsection 3(1), section 4 or subsection 8(1) or 9(1) is payable by a manufacturer if

(a) the manufacturer fails to submit the information and documents required in respect of an application for registration referred to in subsection 76(2) of the Regulations before the date referred to in subsection 76(1) of the Regulations; or

(*b*) the medical device is modified in accordance with section 24 of the Regulations; or

(*c*) the notice of compliance or supplementary notice of compliance in respect of the medical device is suspended or cancelled pursuant to section 40 of the old Regulations as if that section were in effect on the date on which these Regulations come into force

SCHEDULE 1

(Section 4 and 5)

CLASS III MEDICAL DEVICES

Item	Column 1 Application information component	Column 2 Fee ($)
1.	Description of the medical device and the materials used in its construction and packaging, intended use and a summary of reported problems with the medical device in other countries	140
2.	Summary and conclusions of studies to ensure that the medical device meets the safety and effectiveness requirements of the Regulations	1,470
3.	A copy of the medical device label	170
4.	In the case of a near patient *in vitro* diagnostic device, a summary of an investigational test conducted on the	440

Item	Column 1 Application information component	Column 2 Fee ($)
	device using human subjects representative of intended users and under conditions similar to the conditions of use of the device.	

SCHEDULE 2

(Sections 4 and 5)

CLASS IV MEDICAL DEVICES

Item	Column 1 Application information component	Column 2 Fee ($)
1.	Description of the medical device and the materials used in its construction and packaging, intended use and a summary of reported problems with the medical device in other countries	140
2.	Risk assessment and risk reduction measures in respect of the medical device	1,000
3.	specifications of the materials used in the construction and packaging of the medical device	680
4.	Production process specifications for the medical device	510
5.	Quality assurance procedures and specifications and quality plan in respect of the medical device	850
6.	In the case of an *in vitro* diagnostic device, pre-clinical and clinical studies to ensure that the device meets the safety and effectiveness requirements of the Regulations	5,970
7.	In the case of a medical device other than an *in vitro* diagnostic device, pre-clinical and clinical studies to ensure that the device meets the safety and effectiveness requirements of the	7,670

Item	Column 1 Application information component	Column 2 Fee ($)
	Regulations	
8.	Process validation studies to ensure that the Medical device meets the safety and effectiveness requirements of the Regulations	850
9.	Software validation studies to ensure that the medical device meets the safety and effectiveness requirements of the Regulations	2,020
10.	A copy of the medical device label	170
11.	In the case of a medical device, other than an *in vitro* diagnostic device, manufactured from or incorporating animal or human tissue or their derivative, information substantiating that the device meets the safety and effectiveness requirements of the Regulations	2,620
12.	In the case of a near patient *in vitro* diagnostic device, detailed information on an investigational test conducted on the device using human subjects representative of the intended users and under conditions similar to the conditions of use of the device.	2,410